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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,269	12/23/2003	Kurt Nilsson	033972.549252	4452

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,269	NILSSON, KURT	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JM

DETAILED ACTION

Claims 1-9 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2, 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "spacer" in claims 1 and 2, is a term which renders the claims indefinite. This term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what constitutes the said spacer. For example, the structure or name of said spacer is not known.

The term "biologically active" in claims 1 and 2, is a term which renders the claims indefinite. This term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what activity must the said saccharides or compounds possess or exhibit to be considered biologically active.

Claims 6-9 provide for "the use of any compound ...." but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected under the judicially created doctrine of double patenting over claims 1-3 of U. S. Patent No. 6,686,457 B1 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter,

as follows: In claim 1, applicant claims a "Material characterized by that the material contains at least one biologically active di-or trisaccharide or higher oligosaccharide which is covalently bound via a spacer to cross-linked agarose. In claim 2, applicant claims "Material characterized by that the material contains at least one biologically active saccharide which is covalently bound via a spacer to cross-linked matrix." Claim 3, which is drawn to the material according to claim 2 which has been treated by autoclaving.

Nilsson, in claims 1-3, claims: "1. A material comprising a saccharide-spacer-matrix where the saccharide denotes a mono-, di- tri- or higher oligosaccharide, which is glycosidically linked to the matrix via the spacer having the formula:

—O(CH$_2$)$_n$-PhNH—CO—(CH$_2$)$_m$NH—CH$_2$—CH(OH)—CH$_2$—O—,

—O(CH$_2$)$_n$NH— or —N(Ac)—(CH$_2$)$_n$NH—,

where Ac is an acetyl group and n and m is an integer 0, 1, 2, 3, 4, 5, 6, or 7,

or where the spacer contains a mono-, di-, or oligosaccharide, a polysaccharide, a peptide, another oligomeric substance, or a protein.

2. The material according to claim 1 where matrix denotes a plastic or a polysaccharide.

3. The material according to claim 1 which has been autoclaved."

The difference between applicant's composition or material and the composition or material of Nilsson is that applicant's claims a composition or material that contain saccharides that are biologically active and specific matrix. However, Nilsson claimed saccharides and matrix, in general, includes biologically active saccharides and specific matrix such as cross-linked matrix or agarose.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared the material or composition of Nilsson to treat blood comprising saccharide-spacer-matrix and to use specific saccharides such as biologically active

saccharides and specific matrix such as cross-linked matrix or agarose, since Nilsson discloses that biologically active saccharides and matrix, in general, can be used.

One having ordinary skill in the art would have been motivated to have prepare the material or composition of Nilsson to treat blood comprising a saccharide-spacer-matrix and to use specific saccharides such as biologically active saccharides and specific matrix such as cross-linked matrix or agarose, since Nilsson discloses that biologically active saccharides and matrix, in general, can be used.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 09/958,272. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to the method of treating and preventing inflammation in a patient by topical application.

In claim 1, applicant claims a "Material characterized by that the material contains at least one biologically active di-or trisaccharide or higher oligosaccharide which is covalently bound via a spacer to cross-linked agarose. In claim 2, applicant claims "Material characterized

by that the material contains at least one biologically active saccharide which is covalently bound via a spacer to cross-linked matrix."

Nilsson in claim 9, claims a composition of matter represented by the structure:

saacharide - spacer - matrix

wherein : saccharide denotes a saccharide selected from the group consisting of glycoprotein, neoglycoprotein, a glycopeptide, a glycosylated amino acid, a glycolipid, a fragment of the foregoing, a biologically active di - or trisaccharide, and oligosacchaddes;
matrix is a plastic or cross-linked agarose, and the spacer is a member selected from the group consisting of -O(CH2)$_2$PhNH-, -O(CH2)$_n$PhNH-C0- (CH2)mNH-, -N(Ac)-(CH2)$_n$ NH- where Aç is the acetyl group, and -O(CH2)$_n$ NH-, -O(CH2)$_n$ PhNH-CO- (CH2)$_m$NH-CH2-CH(OH)CH2- wherein n is 0 to 4 and m is 1-7.

The difference between applicant's composition or material and the composition or material of Nilsson is that applicant's claims a composition or material that contain spacers, in general. However, Nilsson claims specific spacers.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared the material or composition of Nilsson to treat blood comprising saccharide-spacer-matrix and to use a spacer, since Nilsson discloses that spacers can be used.

One having ordinary skill in the art would have been motivated to have prepare the material or composition of Nilsson to treat blood comprising a saccharide-spacer-matrix and to use a spacer, since Nilsson discloses that spacers can be used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaieda et al. (US 4,839,290).

In claim 1, applicant claims a "Material characterized by that the material contains at least one biologically active di-or trisaccharide or higher oligosaccharide which is covalently bound via a spacer to cross-linked agarose." Kaieda et al. disclose applicant's material which contains at least one biologically active oligosaccharide which is covalently bound via a spacer (epoxy) to cross-linked agarose (epoxy-activated sepharose) (see col. 22, example 5, line 36-68). Kaieda et al.'s refers to their material as an antitumor immunocyte inducing material (see col. 22, example 5, line 36-68). In claim 2, applicant claims "Material characterized by that the material contains at least one biologically active saccharide which is covalently bound via a spacer to cross-linked matrix" .Kaieda et al. disclose applicant's material which contains at least one biologically active saccharide (oligosaccharide) which is covalently bound via a spacer (epoxy) to cross-linked agarose (epoxy-activated sepharose) (see col. 22, example 5, line 36-68).

Claims 2-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Callahan et al. (Immunological Communications, (1975) 4(6), pages 537-52).

In claim 2, applicant claims "Material characterized by that the material contains at least one biologically active saccharide which is covalently bound via a spacer to cross-linked matrix"

Callahan et al. disclose applicant's material which contains at least one biologically active saccharide (a polysaccharide) which is covalently bound via a spacer (a 1,6 hexanediamine spacer) to a cross-linked matrix (sepharose 4b) (see abstract). It should be noted that the examiner considers the sepharose 4b, a cross-linked matrix. Claim 3, which is drawn to the material according to claim 2 which has been treated by autoclaving, is anticipated by Callahan et al. (see abstract). It should be noted that said treatment by autoclaving does not render the claimed material as being different in structure, name from the material that has not being autoclaved. Claim 4 which is drawn to the material according to claim 2, completely or partially filled in an autoclavable column, is also anticipated by Callahan et al., since Callahan et al. material also contains biocompatible antibodies (of the IgG class) (see abstract). It should be noted that said treatment by autoclaving does not render the claimed material as being different in structure, name from the material that has not being autoclaved. Furthermore, it should be noted that claim 4 is a composition claim, and the column (autoclavable or not) which contains the said composition or material does not add to the patentability of the claimed composition. Claim 5 is drawn to a column according to claim 4, which has been treated by autoclaving, is also anticipated by Callahan et al. (see abstract). It should be noted that said treatment by autoclaving does not render the claimed material as being different in structure, name from the material that has not being autoclaved. Furthermore, it should be noted that claim 5 is a composition claim, and the column (autoclavable or not) which contains the said composition or material does not add to the patentability of the claimed composition.

Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagy et al. (US 5,962,422).

In claim 2, applicant claims "Material characterized by that the material contains at least one biologically active saccharide which is covalently bound via a spacer to cross-linked matrix" Nagy et al. disclose applicant's material which contains at least one biologically active saccharide which is covalently bound via a spacer to a cross-linked matrix (see sheet 8, figure 9, last structure). It should be noted that the examiner considers the liposome to which the saccharide-spacer is bound, a cross-linked matrix. Claim 3, which is drawn to the material according to claim 2 which has been treated by autoclaving, is anticipated by Nagy et al. (see abstract). It should be noted that said treatment by autoclaving does not render the claimed material as being different in structure, name from the material that has not being autoclaved.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

March 30, 2005.

ELVIS O. PRICE, PH.D.
PRIMARY EXAMINER